

Alwood, Jim

From: Alwood, Jim
Sent: Wednesday, October 18, 2017 6:43 PM
To: kosuzu
Subject: RE: Reporting of Chemical Substances When Manufactured or Processed as Nanoscale Materials: Draft Guidance (Docket ID No. EPA-HQ-OPPT-2010-0572-0176)

Mr. Irie – See my responses below in red. Let me know if you have follow-up questions.

Jim

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From: kosuzu [mailto:pvmt32249@ares.eonet.ne.jp]
Sent: Wednesday, October 04, 2017 7:16 AM
To: Alwood, Jim <Alwood.Jim@epa.gov>
Subject: Re: Reporting of Chemical Substances When Manufactured or Processed as Nanoscale Materials: Draft Guidance (Docket ID No. EPA-HQ-OPPT-2010-0572-0176)

Dear Mr.Alwood,

We appreciate the opportunity to make inquiry on reporting of chemical substances when manufactured or processed as nanoscale materials.

We confirmed the contents of Q&A, however, we are not able to determine whether the cases described below are the subject of the report on nanomaterials. Please reply to our question.

-Inquiry on Question 1:

In the draft, the particle size of the aggregates and agglomerates greater than 100 nm is not a reportable chemical substance.

Is the particle size of the aggregates and agglomerates greater than 100 nm, which is comprised of plural substances, excluded from the reportable chemical substance?

For example, the particle size of 1 μ m(substance A) is attached to and aggregated with nanoparticle of a different component(substance B) by van der Waals force or electrostatic force.

Is this case excluded from the reportable chemical substance?

If you manufacture, import or process particles that are aggregates or agglomerates greater than 100 nm then reporting is not required. It does not matter what the chemical composition of the material is.

However see the answer to your next question - if at any time you process a chemical substance and the particle size is now less than 100 nm and you meet the other criteria for reporting then reporting would be required for those activities.

-Inquiry on Question 6 and 9:

In the draft, we must report each individual reportable chemical substance included in a mixture.

Are the cases described below excluded from reportable chemical substance, though the particle size of the materials would not be less than 100 nm at a time of the import or the use?

Case 1) Pigments in the case of importing plastic particles (for example, colored pellet, etc) greater than 100 nm with the pigments dispersions less than 100 nm.

Case 2) Pigments and other materials being included in plastic particles greater than 100 nm, which are greater than 100 nm in raw material state, though they possibly would be less than 100 nm when dispersed.

In both cases described above reporting would be required for any processing where the particle size is less than 100 nm when dispersed and you meet the other criteria for reporting.

In the case of a pigment if that chemical has the same intrinsic property (it's still a blue pigment for example when particle size is less than 100 nm) then you would not meet the criteria of unique and novel properties because of its size.

The general principle is that reporting is required any time a chemical that is nanoscale material meets the criteria of the rule – even if at other times in the supply chain it does not meet the criteria of the rule. You only are required to report activities when a chemical meets the criteria of the rule.

-Other inquiry:

In the rule, the rule does not require manufacturers to report certain information that has already reported information required under this rule for EPA's Nanoscale Materials Stewardship Program (NMSP).

Does importer have to report if supplier already reported information under this rule for NMSP?

If yes, what kind of information does importer report?

If you are required to report a chemical substance that meets the criteria of the rule you do not have to report any information already reported to EPA under the NMSP by the supplier. You would report any processing information about the chemical that has not been submitted – and any basic chemical identity information that is reasonably ascertainable. If you have more details about your chemical and your activity I can give you a more specific answer.

Sincerely,
October 4, 2017

Ryuhichi Irie